K071195

JUN 20 2007

510(k) SUMMARY

Prepared as required by CFR 892.1100

Device Name: KHBS version 1.1 (Krishnamurthy Hepato-Biliary Software)

Common Name: Scintillation Gamma Camera-Accessory

Product Code: IYX

510(k) Number: K071195

Submitter Name: ANI-KAL II, LLC

Contact Person: Gerbail T. Krishnamurthy

Contact Person telephone Number: (503)245-9029 or 503)681-1745,
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Device Description: KHBS is an Off the Shelf nuclear hepatology software written on JAVA platform that can be loaded on to a PC. It is used for quantitative analysis and display of planar dicom image data acquired using scintillation gamma camera. The system generates time activity/curves and provides quantitative results of the liver and gallbladder function. It displays images, curves and texts in grey scale or color.

Intended use: KHBS is accessory for quantitative analysis of planar liver and gallbladder function studies acquired in a scintillation gamma camera system. It processes the data and displays images in a format desired by the user. KHBS should be operated only by qualified health care professionals trained with the use of nuclear medicine equipments.

Device Comparison:

Predicate Device	**Manufacturer**	**510(k) Number**
E.CAM/E.Soft	Siemens Medical Solutions USA, Inc	K992731
ICON Computer System	Siemens Medical Solutions USA, Inc	K903315B
ADAC Pegasys	Phillips Medical System	K892358
Hawkeye Option	EL GEMS Ltd/GE Medical	K991841

KHBS is produced specifically for analysis of liver and gallbladder function and incorporates many of known functional parameters. Although many of the functional parameters can be obtained with the Siemens predicate device, it is labor intensive and prone to errors of manual calculations. Similar comments apply to other predicate device from Phillips and GE.

Summary of design control. Risk analysis method includes impact of calculation errors. Since the gamma camera Dicom data provides an organ image to compare to the quantitative results from KHBS, the clinician will be able to pick up any error in calculations. For example, a low gallbladder ejection fraction (GBEF) value should have minor reduction in gallbladder size on the image, and a normal EF should have major reduction in image size. Detailed risk analysis is also incorporated in the original submission.

Device Comparison: The studies obtained with the scintillation gamma camera and analyzed with KHBS were compared with the results obtained with Siemens nuclear medicine software (E.Soft) in our department. Since we do not have GE or Phillips computer system, we did not compare our results with these two systems. However, both of these systems (Phillips K892358 and GE K991841) were quoted as equivalent in the Siemens application for 510(k) submission to the FDA for Software enable analysis of data obtained with a scintillation gamma camera system. Siemens E.Soft and other predicate devices provide basic means of data analysis and most of liver and gallbladder functional parameters have to be calculated manually. It is time consuming and may lead to errors of manual calculation. The following table provides some important similarities and differences between KHBS and Siemens E. Soft system

Table 1. Comparison of parameters between KHBS and Siemens E.Soft system

Parameter	**KHBS**	**Siemens**
Requires	PC	PC
Platform	Java	MS DOS
Deconvolutional analysis	yes	no
HEF	yes	no
T1/2 measurement	auto	manual
GBEF	yes	yes
GBEP	auto	manual
GBER	auto	manual
DGBR Basal	auto	manual
DGBR-CCK	auto	manual
Segmental GBEF	auto	manual
Lobar liver function	auto	mabual
Segmental liver function	yes	no
HPS	auto	manual

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

G.T. Krishnamurthy, M.D.
Manager
ANI-KAL II, LLC
7570 SW West Gate Way
PORTLAND OR 97225

JUN 20 2007

Re: K071195
Trade/Device Name: KHBS v 1.1 (Nuclear Hepatology Software)
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: IYX and LLZ
Dated: April 26, 2007
Received: May 2, 2007

Dear Dr. Krishnamurthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K071195

Device Name:KHBS v 1.1 (Nuclear Hepatology software)

Indications for Use: KHBS is an "Off the Shelf" software used for quantitative analysis of liver and gallbladder function studies obtained with a scintillation gamma camera. The Dicom image data obtained with the scintillation gamma camera is transferred to the software loaded on to a network PC and analyzed by a person familiar with the use of nuclear medicine equipment.

Prescription Use ✓X AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRB~ Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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